

(19)



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(11)

EP 0 588 965 B1

(12)

EUROPEAN PATENT SPECIFICATION

(45) Date of publication and mention
of the grant of the patent:
10.09.1997 Bulletin 1997/37

(21) Application number: 92914416.0

(22) Date of filing: 10.06.1992

(51) Int. Cl.⁶: **A61M 5/00**

(86) International application number:
PCT/US92/04875

(87) International publication number:
WO 92/22347 (23.12.1992 Gazette 1992/32)

(54) COLLECTION DEVICE

SAMMELVORRICHTUNG
DISPOSITIF DE COLLECTE

(84) Designated Contracting States:
AT BE CH DE DK ES FR GB IT LI NL SE

(30) Priority: 11.06.1991 US 714546

(43) Date of publication of application:
30.03.1994 Bulletin 1994/13

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(56) References cited:

DE-B- 2 043 795	GB-A- 2 021 418
US-A- 3 559 647	US-A- 3 891 416
US-A- 4 014 329	US-A- 4 490 331
US-A- 4 642 089	US-A- 4 662 906
US-A- 5 024 613	US-A- 5 127 900
US-E- 29 877	

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Description

TECHNICAL FIELD

The present invention relates to fluid collection devices and in particular to collection systems with separable reservoirs for removal and collection of fluids or gases from patients, such as from the chest cavity, by means of pressure differentials, and for possible return to the patient.

BACKGROUND ART

Drainage containers have been known for use in various medical procedures. For many years, the standard apparatus for performing the evacuation of the pleural cavity was a collection system known as the "3-bottle set-up" which includes a collection bottle, a water seal bottle and a suction control bottle. A catheter runs from the patient's pleural cavity to the collection bottle, and the suction bottle is connected by a tube to a suction source. The three bottles are connected in series by various tubes to apply suction to the pleural cavity to withdraw fluid and air and thereafter discharge the same into the collection bottle. Gases entering the collection bottle bubble through water in the water seal bottle. The water in the water seal also usually prevents the back flow of air into the chest cavity.

The 3-bottle set-up lost favor with the introduction of an underwater seal collection system sold under the name "Pleur-evac"® in 1966 by Deknatel Inc. (a more detailed description of the need for and the proper use of chest collection devices is presented in the Deknatel Inc. Pleur-evac® publication entitled "Physiology of the Chest and Thoracic Catheters: Chest Drainage Systems No. 1 of a series from Deknatel" (1985) which is incorporated herein in its entirety). U.S. Patent Nos. 3,363,626; 3,363,627; 3,559,647; 3,683,913; 3,782,497; 4,258,824; and Re. 29,877 are directed to various aspects of the Pleur-evac® system which over the years has provided improvements that eliminated various shortcomings of the 3-bottle set-up. These improvements have included the elimination of variations in the 3-bottle set-up that existed between different manufacturers, hospitals and hospital laboratories. Such variations include bottle size, tube length and diameter, stopper material and the like.

Among the features of the Pleur-evac® system which provide its improved performance are employment of 3-bottle techniques in a single, pre-formed, self-contained unit. The desired values of suction are generally established by the levels of water in the suction control bottle and the water seal bottle. These levels are filled according to specified values prior to the application of the system to the patient. A special valve referred to as the "High Negativity Valve" is included which is employed when the patient's negativity becomes sufficient to threaten loss of the water seal. Also, a "Positive Pressure Release Valve" in the large arm of the water

seal chamber works to prevent a tension pneumothorax when pressure in the large arm of the water seal exceeds a prescribed value because of suction malfunction, accidental clamping or occlusion of the suction tube. The Pleur-evac® system is disposable and helps in the battle to control cross-contamination.

Despite the advantages of the Pleur-evac® system over the 3-bottle set-up and the general acceptance of the device in the medical community, there remains a continuing need to improve the convenience and performance of chest collection systems and to render such systems compact.

Also, in a number of surgical procedures referred to in the art as cardiopulmonary bypass operations, it is necessary to interrupt and suspend the normal functioning of the patient's heart and lungs and to temporarily replace the function of these organs with artificial blood handling and treating units in a life-sustaining extracorporeal blood flow circuit. In these procedures, the main body of the patient's blood, which is called the venous return stream, is typically withdrawn from the patient through a venous cannula inserted into the right atrium, collected in a venous reservoir, and then passed through a blood pump (artificial heart), blood oxygenator (artificial lung) and arterial blood filter before being returned to the patient through an aortic cannula inserted into the aorta distal to the aorta arch. In conventional practice, the venous reservoir is a flexible transparent bag with a blood outlet in the bottom. Additionally, in typical practice, patient's blood from the surgical field, which is called cardiotomy blood, is gathered in one or more cardiac vacuum suckers and defoamed, filtered and collected in a cardiotomy reservoir and filter device. The treated cardiotomy blood is then conducted to the venous reservoir, where it is combined with the venous return blood.

In addition, blood supplied to a patient must usually be purified by filtration to avoid jeopardizing the patient. The blood may be obtained from the patient during various surgical procedures when it is advantageous to store excess blood outside the body to facilitate the surgical procedures, or in blood conservation by scavenging the blood from the wound. Such blood is usually collected in a cardiotomy reservoir and purified there by passage through a filter unit within the reservoir. The blood passing through the cardiotomy reservoir must not only be purified of undesirable particulate matter such as surgical debris, but must also be freed of entrained air bubbles before being returned to the patient.

It is known to provide in a cardiotomy reservoir a filter unit including means for screening out particulate matter, and means for defoaming the blood to remove the air trapped therein. Examples of such known devices include those disclosed in U.S. Patent Nos. 3,507,395 and 3,768,653. The former discloses a cardiotomy reservoir comprising a chamber containing a plate surrounded by a fibrous filter element contained in a nylon bag. The plate first spreads the incoming blood

to remove the air bubbles therefrom which are vented, or drawn by vacuum, from the chamber, and the filter removes solid particles from the blood as it passes therethrough before leaving the chamber. U.S. Patent No. 3,768,653 discloses a cardiotomy reservoir comprising a tubular chamber having a tangential inlet for the blood which is directed onto a filter across one end of the chamber which also contains a conical air filter.

U.S. Patent No. 4,642,089 discloses a unitary device for treatment and collection of blood from two different sources. Blood enters into the top of a housing and is directed downward and inward by a funnel. At the bottom of the funnel a frustoconical member with fins directs the blood downward and outward.

The preamble of claim 1 reads on the disclosure of U.S. Patent No. 4,642,089.

Many other filtration systems are known for filtering blood and many use multiple layer elements to remove unwanted materials from the blood as it passes through the layers. U.S. Patent No. 3,765,536 and U.S. Patent No. 3,765,537 disclose a multiple layer blood filter elements including one comprising a first layer of coarse polypropylene netting, a second downstream layer of open-mesh polyester, a third spacer layer of polypropylene netting, a fourth microporous layer and a fifth polypropylene netting spacer layer.

An object of the invention is to provide an apparatus for receiving fluids from a patient, wherein the fluid flow path is separate from the released gas escape path.

The object is achieved by the features of claim 1.

The invention provides an improved reservoir for use alone or with a collection device which provides additional improvements to presently available containers.

The present invention is directed to an apparatus for receiving fluids from a patient comprising a housing having an inlet for entry of fluids into the housing and an outlet for exit of fluids from the housing; and flow means disposed within the housing for at least directing the fluids entering through the inlet to flow in at least a predetermined first direction and in a predetermined second direction. The flow means comprises first rib member disposed adjacent the inlet and being configured and dimensioned so that at least a first portion of fluid falls upon the first rib member and is thereby directed along the first predetermined direction; and second rib member disposed adjacent the first rib member and being configured and dimensioned so that the at least first portion of fluid and the remaining portion of the fluid entering through the inlet falls upon the second rib and is thereby directed along the second predetermined direction.

Preferably, the flow means comprises a plurality of rib members disposed adjacent the inlet and each other and being configured and dimensioned so as to provide a corresponding plurality of predetermined directions in which at least portions of the fluids can flow.

The apparatus further comprising defoamer means configured and dimensioned so as to be disposed within

the housing and in fluid communication with the fluid directed by the flow means prior to passing through the outlet.

In a preferred embodiment, an apparatus for receiving at least blood from a body cavity, comprises housing for collecting at least blood from a body cavity, the housing including an inlet for fluid communication with the body cavity, the housing including a first outlet for returning blood to the body and a second outlet for coupling to a suction source; and flow means being configured and dimensioned so as to be disposed within the housing and so as to direct at least a portion of the blood entering through the inlet into a first predetermined direction and the remaining portion of the blood entering through the inlet and the first directed portion in at least a second predetermined direction within the housing.

The flow means comprises a plate member disposed adjacent the inlet and having a plurality of rib members disposed on the respective plate member so as to divert the flow of blood from the direction in which the blood enters the housing through the inlet in at least the first and the second predetermined directions.

The rib members can also be disposed on the respective plate member so as to direct the flow of blood in a corresponding plurality of predetermined directions. Preferably the rib members are disposed generally transversely to the plate member which has a plurality of apertures disposed so that each rib member has a corresponding aperture adjacent thereto and being generally upstream of the respective rib member.

The apparatus additionally comprises defoamer means configured and dimensioned so as to be disposed within the housing such that the blood passes through the defoamer means before exiting through the first outlet for return to the body. Also, the apparatus further comprises a mount therefor comprising first body member having a generally C-shaped first end portion configured and dimensioned for attachment to a support; and second body member having a first end portion which is configured and dimensioned to receive and retain the housing, the first body member and the second body member being coupled to each other at their respective second end portions for rotational relative movement in discrete.

The present invention also is directed to a collection device for receiving, collecting and returning bodily fluids, comprising reservoir including housing having an inlet for entry of fluids into the housing and an outlet for exit of fluids from the housing; and flow means disposed within the housing for at least directing the fluids entering through the inlet to flow in at least a predetermined first direction and in a predetermined second direction; and suction control means having a first outlet for fluidly communicating with the second outlet of the reservoir housing and having a second outlet for fluidly communicating with the ambient. Preferably, the flow means comprises a plurality of rib members disposed adjacent the inlet and each other and being configured and

dimensioned so as to provide a corresponding plurality of predetermined directions in which at least portions of the fluids can flow.

The collection device further comprises seal means fluidly coupled between the reservoir and the suction control chamber so as to prevent back flow of air to the patient.

Additionally, defoamer means configured and dimensioned so as to be disposed within the housing is provided in fluid communication with the fluid directed by the flow means prior to passing through the outlet.

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention is described in greater detail hereinbelow, with reference to the drawings wherein:

FIG. 1 is a front end view of a reservoir according to the present invention.

FIG. 2 is a top view of the reservoir of FIG. 1.

FIG. 3 is a side view of the reservoir of FIG. 1 supported in a hanging position with a pole mount according to the present invention.

FIG. 4 is a cross-sectional view taken along the lines 4-4 of FIG. 2 of the reservoir according to the present invention.

FIG. 5 is a cross-sectional view taken along the lines 5-5 of FIG. 4.

FIG. 6 is slightly enlarged and partially exposed view of the plate and rib member of the filter assembly of the reservoir according to the present invention.

FIG. 7 is a top view of the filter assembly of FIG. 6.

FIG. 8 is an end view of the filter assembly of FIG. 6.

FIG. 9 is an enlarged side view of the plate member with ribs of the flow diverter according to the present invention illustrating the direction of the flow of fluids therealong.

FIG. 10 is a front view of a collection/reservoir device supported in a hanging position with a pole mount according to the present invention.

FIG. 11 is a front view of the collection/reservoir device of FIG. 10 illustrating a stabilizing support stand shown rotated to a locked operative body stabilizing position.

FIG. 12 is a top view of the collection/reservoir device of FIG. 11.

FIG. 13 is a front view of the collection/reservoir device of FIG. 10 coupled with a separate autotransfusion bag.

FIG. 14 is a top view of the collection/reservoir device and separate autotransfusion bag of FIG. 13.

FIG. 15 is a top view of the pole mount in various operational positions according to the present invention.

FIG. 16 is a side view of the pole mount of FIG. 15.

FIG. 17 is an enlarged and partially exposed top

view of the pole mount of FIG. 15 illustrating the ratchet mechanism.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

In the description which follows, any reference to either orientation or direction is intended primarily for the purpose of illustration and is not intended in any way as a limitation of the scope of the present invention.

Referring to FIG. 1, a reservoir 10 according to the present invention, is formed of a housing 12 having a configuration as shown. The reservoir 10 has an upper open end which is closed by a cover 14 that has a raised central portion 16 as more clearly shown in FIG. 2. Four inlet ports 18 extend from the raised portion 16 three of which are shown coupled to suitable tubings 20 that can be coupled at their other end to the patient. One of the ports 18 is shown with a cap 22 which is provided with the reservoir prior to use. The raised portion 16 has a plurality of passageways therein which are coupled to the ports 18 and which ultimately couple with the interior of the housing 12. Such cap configuration is well known and is available in the Shiley "3L CARDIF PLUS Cardiotomy Reservoir With Filter", hereinafter the Shiley reservoir. The cover 14 includes a vacuum or vent fitting 24 which allows for attachment to a vacuum source to provide suction at the ports 18 or allows pressure to be relieved from the reservoir 10 in the event that the ports 18 were connected to a pressure source such as a roller pump. A quick prime fitting 26 is provided on the raised portion 16 which allows, as described in more detail below, for conveniently priming the filter 40 with a fluid. A pair of luer fittings 28 positioned on the raised portion 16 and a second pair of luer fittings 28 positioned on the cover 14 provide inlets for adding solutions to the interior of the housing 12. A safety valve 30 allows excess positive pressure to be relieved from the reservoir 10 in the event that the vent/vacuum port become occluded. The safety valve 30 will also allow atmospheric air to enter the reservoir 10 if excessive vacuum is drawn on the vent/vacuum port. A post operative collection inlet port 32 is positioned centrally of the raised portion 16 and allows blood to be collected post operatively through a patient tube. As shown in FIG. 1, the inlet port 32 can be covered by a protective cap 34 when not in use. The inlet ports 18 are used for intraoperative blood collection with suction wands of the type known to those skilled in the art. The inlet ports 18 can also be used with ventricular vent devices.

Referring to FIG. 1, the housing 12 includes an exit port 36 which can be connected to a suitable tubing 38 that provides an outlet to the bypass circuit, for example, during bypass heart operations. In this manner, collected blood within the housing 12 can be returned to the cardiopulmonary bypass circuit or post operatively to continuously reinfuse the collected blood to the patient.

Positioned within the housing 12 is a filter and/or

defoamer assembly 40 which both filters and defoams the collected blood within the housing 12. The filter or defoamer assembly 40 is generally similar to that which is found in the aforementioned Shiley reservoir and as generally discussed in U.S. Patent Nos. 4,642,089, 4,737,139 and 4,743,371 which are incorporated herein in their entirety.

The filter assembly 40, as shown particularly in FIGS. 1, 4 and 6, includes a polyester tricot outer sock 42 which encloses a 6.4 mm (quarter-inch) foam member 44 having a porosity of 3.9 pores per cm [10 pores per inch (ppi)]. This, in turn, encloses a depth filter 46 which is formed of well-known filter material having about a 40 micron porosity. Next, a 12.7 mm (one-half inch) foam 48 is positioned inwardly of the depth filter 46 and has a porosity of 11.8 pores per cm (30 ppi). The filter assembly 40 separates the housing 12 into an inner region 43 and an outer region 45 which itself is bounded by the wall of the housing 12.

The filter assembly 40 encloses a flow director which includes a rectangular plate member 50 which has three like configured apertures of a parallelogram configuration 52 and an upper aperture 54 which is of a trapezoidal configuration. Positioned within each aperture 52, 54 is a generally rectangular rib 56, 57 which extends laterally on both sides of the apertures 52, 54. Preferably, the ribs 56, 57 are transversely positioned relative to the plate member 50 in predetermined directions as shown in FIG. 9. The ribs 56, 57 can be glued or otherwise fastened within the apertures 52 or can be injection molded integrally with the plate member 50. The upstream portion of the plate member 50 is positioned within a funnel 58 as shown more clearly in FIGS. 6, 7 and 9 which, in turn, is positioned below the inlet ports that collectively converge upon the funnel 58. As shown in FIG. 7, the plate member 50 is positioned centrally of an oval opening 60 within the funnel 58, that generally slopes from its peripheral edge 63 down and inwardly in a downstream direction within the housing 12. As shown in FIG. 4, the open end of the filter assembly 40 is fitted up against the funnel 58 and secured thereabout by a tie wrap 47 as shown in FIG. 1. In this manner, inner region 43 is fluidly coupled to the ports 18 and the various inlets on the raised portion 16.

In operation, fluids including, for example, blood and/or gases from a patient will be collected through the tubings 20, through ports 18, through the common inlet within the raised portion 16 and down onto the funnel 58 which will thereby direct the fluid and blood and gases down through the opening 60 and onto the ribs 56, 57 in the direction of the arrows as shown in FIG. 9. As shown therein, some of the blood and gases will fall upon the first rib 56 positioned adjacent the funnel 58 and opening 60. Gases that are entrained within this fluid or blood will escape upwardly in the direction of the arrows as shown and can also pass through the apertures 52 and 54. Similarly, the blood can also pass through the apertures 52 and 54 depending on the orientation of the plate member 50 but will eventually fall upon at least

one or more ribs 56. The first rib has a downstream edge 59. Thereafter, the portion of blood falling upon the first rib 56 will fall off the edge 59 onto the next adjacent rib 57 which will also receive the remaining blood passing through the opening 60. The blood falling together with the gases upon the second rib 57 will pass onto the third rib 57 and thereafter onto the fourth. If desired, additional ribs 57 can be provided in alternative orientations. Finally, the blood collected within the region 43 containing the plate member 50 will pass through the filter assembly 40 and into the region 45 between filter assembly 40 and the wall of housing 12. In this manner, the blood can be either stored or reinfused at the desired time to the patient through port 36 and tubing 38. The housing 12 also includes a recessed region 61 which allows the use of the reservoir with a collection device as will be discussed in greater detail hereinbelow.

Referring to FIG. 3, the reservoir 10 is shown supported from a utility pole 62 by a pole mounting bracket 64. As shown more clearly in FIGS. 15-17, the utility pole mount 64 includes a generally U-shaped arm 66 which has an inner configuration suitable to receive the outer wall of housing 12. In addition, the cover 14 overhangs the housing 12 to provide a ledge 67 as shown in FIG. 1 and which is suitably sized so as to rest over the upper surface of the U-shaped arm portion 66. The utility pole bracket also includes a C-shaped clamp 68 which is positioned about the pole 62 and held thereto by a threaded bolt 70 with a knob 71. The bolt 70 passes through a like threaded bore (not shown) in the C-shaped clamp 68 and can be advanced by turning knob 71. The pole arm 66 and clamp 68 are pivotally or rotationally attached by a pin 72 which is press fitted through a bore in clamp 68 that lines up with a like sized bore in arm 66 when aligned as shown in FIG. 15. As shown in FIGS. 16 and 17, the clamp 68 has a recess 74 into which the stem 76 of arm 66 is positioned and held there in place by means of pin 72. The stem 76 ends in a series of spaced grooves 78. The clamp 68 has a passageway 80 which houses or receives a pin 82 with a reduced spherical end 83 and a spring 84 which biases the pin outwardly against the grooves 78 in stem 76. In this manner, the clamp 68 can be securely fastened to the pole 62 and the reservoir 10 can be retained within arm 66. Then, the arm 66 can be ratcheted by means of grooves 78 and pin 83 to a desired discrete position corresponding to the respective spaced grooves 78.

Referring to FIG. 10, an embodiment of the present invention is shown. In this embodiment, the reservoir 10 is supported by the pole mount 64 to a pole 62. The reservoir 10 is also coupled to a collection device 86 which has a pedestal 88 that is configured and dimensioned to be slotted within the recessed portion 61 of reservoir 10. The collection device 86 is generally of the type illustrated and discussed in U.S. Patent Nos. 4,784,642 and 4,955,874 which are incorporated herein in their entirety. The operation and structure of such collection

devices is set forth in the aforementioned patents. According to the embodiment of FIG. 10, the vent/vacuum port 24 is coupled by connected tubing 90 to collection device 86 and, in particular, to the water seal chamber portion 92. The collection device 86 also has a suction control chamber 94. In addition, the collection device 86 includes a floor stand 96 of the type shown and discussed in U.S. Patent No. 4,955,873, which is also incorporated herein in its entirety. The floor stand or stabilizing member 96 can be rotated in the position as shown in FIG. 11 which illustrates the collection device 86 and reservoir 10 in a supported position on the floor. As shown in FIG. 12, the collection device 86 includes a positive pressure relief valve 98 and a high negativity relief valve 99 of the types which are generally known to those skilled in the art. The connector tubing 90 provides a jumper connection or a vacuum jumper between the reservoir 10 and the collection device or suction module 86. A tubing 100 from collection device 86 is coupled to a vacuum source (not shown) and provides suction into reservoir 10. The central port 32 is coupled to the patient by tubing 102. In the embodiment illustrated in FIG. 12, the cover 14 includes a safety check valve 103. As illustrated in FIGS. 10 and 11, the water seal 104 and the suction control manometer 106 are of the type generally discussed and illustrated in the aforementioned patents. Also, the outlet 36 on reservoir 10 in FIG. 10 is connected to the patient by a quick coupling connector 107 when utilized postoperatively unlike the tubing 38 of FIG. 1, which is used intraoperatively.

Referring now to FIGS. 13 and 14, the reservoir 10 and collection device or suction module 86 of FIG. 11 in the floor stand supported configuration is illustrated together with an auto transfusion bag 108 which is supported within a frame 110. In this configuration, the autotransfusion inlet is coupled by tubing 112 to the patient. Flow through tubing 112 is controlled by a clamp 114. The suction is provided by means of tubing 116 which is controlled by clamp 118 and is ultimately coupled to the central port 32 and the raised section 16. The operation and structure of the autotransfusion bag are described and illustrated in U.S. Patent Nos. 4,443,220 and 4,756,501 which are incorporated herein in their entirety. A coupling device 120 is shown in FIG. 13 and is of the type illustrated and described in commonly assigned U.S. Patent No. 4,955,874 which is also incorporated in its entirety. The coupling device 120 provides a sampling injection port which allows for multiple hypodermic needle punctures while maintaining self-sealing capability.

In yet another alternative embodiment, the collection device 86 and reservoir 10 can be provided with hangers as described and illustrated in U.S. Patent 4,756,501, which is incorporated in its entirety, so as to provide a hanging support from a horizontal rail.

As noted above regarding the operation of the reservoir 10, blood which enters through opening 60 is diverted from a unidirectional flow into various alternat-

ing paths providing gentle flow with minimal turbulence. In addition, such alternative paths allow for the escape of gases from the blood and fluids. Upon passage of the blood and fluids through the filter assembly 40, the filtered blood is available for return to the patient through the outlet port 36 in tubing 38 through a filter bypass circuit. In the configuration of the reservoir 10 employed with the collection device 86 in FIGS. 6-8, the reservoir can receive the fluids and blood and gases and upon filtration return the same immediately to the patient through the tubing 38. Alternatively, the exit port 36 can be sealed and the fluids collected within reservoir 10 until further need. In the case of collection from a plural cavity as described in U.S. Patent No. 4,784,642, the reintroduction of fluids to the patient may be delayed in accordance with well-known medical procedures. Finally, in the configuration illustrated in FIG. 12, the reservoir 10 and collection device 86 can be incorporated with an autotransfusion bag 108 in a stand alone wire frame unit 110 similar to the manner shown and discussed in U.S. Patent No. 4,756,501.

The present invention has been described in detail with particular emphasis on the preferred embodiments thereof.

Claims

1. Apparatus (10) for receiving fluids from a patient, comprising:

- a) a housing (12) having an inlet (18) for entry of fluids in to said housing (12) and an outlet (36) for exit of fluids from said housing (12); and

- b) flow means (50) disposed within said housing (12) for at least directing the fluids entering through said inlet (18) to flow along predetermined directions,

characterized in that said flow means (50) comprises:

- 1) a first rib member (56) disposed adjacent and generally downstream of said inlet (18) and positioned along a first predetermined direction and being configured and dimensioned so that at least a first portion of the fluid entering through the inlet (18) falls upon said first rib member (56) and is thereby directed along said first predetermined direction of said first rib member (56); and

- 2) a second rib member (57) disposed adjacent and generally downstream of said first rib member (56) and positioned along a second predetermined direction different than said first predetermined direction and being configured and dimensioned so that the at least first portion of the fluid and the remaining portion of the fluid entering

through said inlet (18) fall upon said second rib member (57) and are thereby directed along said second predetermined direction of said second rib member (57).

2. The apparatus (10) according to claim 1, wherein said flow means (50) comprises a plurality of rib members (56, 57) disposed adjacent said inlet (18) and each other and being configured and dimensioned so as to provide a corresponding plurality of predetermined directions in which at least portions of the fluids can flow.
3. The apparatus (10) according to claim 1 further comprising defoamer means (40) configured and dimensioned so as to be disposed within said housing (12) and in fluid communication with the fluid directed by said flow means (50) prior to passing through said outlet (36).
4. The apparatus (10) according to claim 1, wherein the fluid is at least blood from a body cavity and the housing (12) collects the at least blood from the body cavity, said housing inlet (18) being in fluid communication with the body cavity, said housing outlet including a first outlet (36) for returning blood to the body and a second outlet (24) for coupling to a suction source (86), and wherein the flow means further comprises a plate member (50) disposed adjacent and generally downstream of said inlet (18), said at least first (56) and second rib members (57) being disposed on the plate member (50).
5. The apparatus (10) according to claim 4, wherein said rib members (56,57) are disposed on said respective plate member (50) so as to direct the flow of blood in a corresponding plurality of predetermined directions.
6. The apparatus (10) according to claim 5, wherein said rib members (56,57) are disposed generally transversely to said plate member (50).
7. The apparatus (10) according to claim 6, wherein said plate member (50) has a plurality of apertures (54,52) disposed thereon so that each rib member (56,57) has a corresponding aperture (54,52) adjacent thereto and being generally upstream of said respective rib member (56,57).
8. The apparatus (10) according to claim 4 further comprising defoamer means (40) configured and dimensioned so as to be disposed within said housing (12) such that the blood passes through said defoamer means (40) before exiting through said first outlet (36) for return to the body.
9. The apparatus (10) according to claim 4 further comprising a mount (64) therefor comprising:

a. a first body member (68) having a generally C-shaped first end portion configured and dimensioned for attachment to a support (62); and

b. a second body member (66) having a first end portion which is configured and dimensioned to receive and retain said housing (12), said first body member (68) and said second body member (66) being coupled to each other at their respective second end portions for rotational relative movement in discrete positions.

10. The apparatus (10) of claim 1, wherein the apparatus (10) includes a collection device (86) for receiving, collecting and returning bodily fluids, said apparatus (10) comprising:

a reservoir which includes the housing (12) and the flow means (50), said housing outlet including a first outlet (36) for exit of fluids from said housing and a second outlet (24) for coupling to a suction source (90), and suction control means (94) having a first outlet (90) for fluidly communicating with said second outlet (24) of said reservoir housing (12) and having a second outlet (98) for fluidly communicating with the ambient.

11. The apparatus (10) according to claim 10, wherein said flow means (50) comprises a plurality of rib members (56,57) disposed adjacent said inlet (18) and each other and being configured and dimensioned so as to provide a corresponding plurality of predetermined directions in which at least portions of the fluids can flow.
12. The apparatus (10) according to claim 10 further comprising seal means (104) fluidly coupled between said reservoir and said suction control chamber (94) so as to prevent back flow of air to the patient.
13. The apparatus (10) according to claim 10 further comprising defoamer means (40) configured and dimensioned so as to be disposed within said housing (12) and in fluid communication with the fluid directed by said flow means (50) prior to passing through said first outlet (36).
14. The apparatus (10) of claim 10, wherein the housing (12) is for collecting at least blood from a body cavity, said housing inlet (18) for fluid communication with the body cavity, said first housing outlet (36) for returning blood to the body, and said flow means comprising a plate member (50) disposed adjacent and generally downstream of said inlet (18), said at least first and second rib members (56,57) being disposed on the plate member (50) along either the first predetermined direction or

along the second predetermined direction so as to divert the flow of blood from the direction in which the blood enters the housing (12) through said inlet (18) along at least said first and said second predetermined directions.

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15. The apparatus (10) according to claim 14, wherein said rib members (56,57) are disposed on said respective plate member (50) so as to direct the flow of blood in a corresponding plurality of predetermined directions.

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16. The apparatus (10) according to claim 15, wherein said rib members (56,57) are disposed generally transversely to said plate member (50).

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17. The apparatus (10) according to claim 16, wherein said plate member (50) has a plurality of apertures (54,52) disposed so that each rib member (56,57) has a corresponding aperture (54,52) adjacent thereto and being generally upstream of said respective rib member (56,57).

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18. The apparatus (10) according to claim 14, further comprising seal means (104) fluidly coupled between said reservoir (12) and said suction control chamber (94) so as to prevent back flow of air to the patient.

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19. The apparatus (10) according to claim 14 further comprising defoamer means (40) configured and dimensioned so as to be disposed within said housing (12) and in fluid communication with the fluid directed by said flow means (50) prior to passing through said outlet (36).

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Patentansprüche

1. Vorrichtung (10) zur Aufnahme von Fluiden von einem Patienten mit:

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a) einem Gehäuse (12), das einen Einlaß (18) zum Eintritt von Fluiden in das Gehäuse (12) und einen Auslaß (36) zum Austritt von Fluiden aus dem Gehäuse (12) aufweist; und

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b) einer Strömungseinrichtung (50), die in dem Gehäuse (12) angeordnet ist, um die Fluide, die durch den Einlaß (18) eintreten, zumindest auszurichten, damit sie entlang bestimmter Richtungen strömen, dadurch gekennzeichnet, daß die Strömungseinrichtung (50) aufweist:

50

1) ein erstes Rippenelement (56), das benachbart zu und im großen und ganzen stromab von dem Einlaß (18) angeordnet und entlang einer ersten bestimmten Richtung positioniert und derart gestaltet und

55

bemessen ist, daß zumindest ein erster Teil des Fluids, das durch den Einlaß (18) eintritt, auf das erste Rippenelement (56) fällt und dabei entlang der ersten bestimmten Richtung des ersten Rippenelements (56) gelenkt wird; und

2) ein zweites Rippenelement (57), das benachbart zu und im großen und ganzen stromab von dem ersten Rippenelement (56) angeordnet und entlang einer zweiten bestimmten Richtung, die anders als die erste bestimmte Richtung ist, positioniert und derart gestaltet und bemessen ist, daß der zumindest erste Teil des Fluids und der restliche Teil des Fluids, der durch den Einlaß (18) eintritt, auf das zweite Rippenelement (57) fällt und dadurch entlang der zweiten bestimmten Richtung des zweiten Rippenelements (57) gelenkt wird.

2. Vorrichtung (10) nach Anspruch 1, wobei die Strömungseinrichtung (50) mehrere Rippenelemente (56, 57) aufweist, die zu dem Einlaß (18) und zueinander benachbart angeordnet und gestaltet und bemessen sind, um mehrere entsprechende bestimmte Richtungen zu schaffen, in denen zumindest Teile der Fluide strömen können.

3. Vorrichtung (10) nach Anspruch 1, die desweiteren eine Entschäumeinrichtung (40) aufweist, die gestaltet und bemessen ist, um in dem Gehäuse (12) und in Fluidverbindung mit dem Fluid angeordnet zu werden, das durch die Strömungseinrichtung (50) gelenkt wird, bevor es durch den Auslaß (36) tritt.

4. Vorrichtung (10) nach Anspruch 1, wobei das Fluid zumindest Blut aus einer Körperhöhle umfaßt, und das Gehäuse (12) das Blut aus der Körperhöhle sammelt, wobei der Gehäuseeinlaß (18) in Fluidverbindung mit der Körperhöhle steht, wobei der Gehäuseauslaß einen ersten Auslaß (36) zur Rückführung von Blut zu dem Körper und einen zweiten Auslaß (24) zum Anschluß an eine Saugquelle (86) aufweist, und wobei die Strömungseinrichtung desweiteren ein Plattenelement (50) aufweist, das benachbart zu und im großen und ganzen stromab von dem Einlaß (18) angeordnet ist, wobei zumindest das erste (56) und das zweite Rippenelement (57) an dem Plattenelement (50) angeordnet sind.

5. Vorrichtung (10) nach Anspruch 4, wobei die Rippenelemente (56, 57) an dem jeweiligen Plattenelement (50) angeordnet sind, um die Blutströmung in mehrere entsprechende bestimmte Richtungen zu lenken.

6. Vorrichtung (10) nach Anspruch 5, wobei die Rip-

peneelemente (56, 57) im großen und ganzen quer bzw. transversal zu dem Plattenelement (50) angeordnet sind.

7. Vorrichtung (10) nach Anspruch 6, wobei das Plattenelement (50) eine Vielzahl von Öffnungen (54, 52) aufweist, die daran derart angeordnet sind, daß jedes Rippenelement (56, 57) eine entsprechende Öffnung (54, 52) hat, die dazu benachbart und im großen und ganzen stromauf des jeweiligen Rippenelements (56, 57) liegt.
8. Vorrichtung (10) nach Anspruch 4, die desweiteren eine Entschäumeinrichtung (40) aufweist, die gestaltet und bemessen ist, um in dem Gehäuse (12) derart angeordnet zu werden, daß das Blut durch die Entschäumeinrichtung (40) tritt, bevor es durch den ersten Auslaß (36) zur Rückführung zu dem Körper austritt.
9. Vorrichtung (10) nach Anspruch 4, die desweiteren eine Befestigung (64) dafür aufweist, mit:
 - a. einem ersten Gehäuseelement (68) mit einem im großen und ganzen C-förmigen ersten Endteil, das zur Befestigung an einer Stütze (62) gestaltet und bemessen ist; und
 - b. einem zweiten Gehäuseelement (66) mit einem ersten Endteil, das gestaltet und bemessen ist, um das Gehäuse (12) aufzunehmen und zu halten, wobei das erste Gehäuseelement (68) und das zweite Gehäuseelement (66) an ihren jeweiligen zweiten Endteilen für eine relative Drehbewegung in diskreten Stellungen miteinander verbunden sind.
10. Vorrichtung (10) nach Anspruch 1, wobei die Vorrichtung (10) eine Sammeleinrichtung (86) zum Aufnehmen, Sammeln und Rückführen von Körperfluiden aufweist, wobei die Vorrichtung (10) aufweist:

einen Behälter, der das Gehäuse (12) und die Strömungseinrichtung (50) umfaßt, wobei der Gehäuseauslaß einen ersten Auslaß (36) zum Austritt von Fluiden aus dem Gehäuse und einen zweiten Auslaß (24) zum Anschluß an eine Saugquelle (90) aufweist, und

eine Saugregleinrichtung (94) mit einem ersten Auslaß (90) zur Fluidverbindung mit dem zweiten Auslaß (24) des Behältergehäuses (12) und mit einem zweiten Auslaß (98) zur Fluidverbindung mit der Umgebung.
11. Vorrichtung (10) nach Anspruch 10, wobei die Strömungseinrichtung (50) mehrere Rippenelemente (56, 57) aufweist, die zu dem Einlaß (18) und zuein-

ander benachbart angeordnet und gestaltet und bemessen sind, um mehrere entsprechende bestimmte Richtungen zu schaffen, in denen zumindest Teile der Fluide strömen können.

12. Vorrichtung (10) nach Anspruch 10, die desweiteren eine Dichtungseinrichtung (104) aufweist, die zwischen dem Behälter und der Saugregelkammer (94) fluidverbunden ist, um einen Rückfluß von Luft zu dem Patienten zu verhindern.
13. Vorrichtung (10) nach Anspruch 10, die desweiteren eine Entschäumeinrichtung (40) aufweist, die gestaltet und bemessen ist, um in dem Gehäuse (12) und in Fluidverbindung mit dem Fluid angeordnet zu werden, das durch die Strömungseinrichtung (50) gelenkt wird, bevor es durch den ersten Auslaß (36) austritt.
14. Vorrichtung (10) nach Anspruch 10, wobei das Gehäuse (12) zum Sammeln von zumindest Blut aus einer Körperhöhle, der Gehäuseeinlaß (18) zur Fluidverbindung mit der Körperhöhle und der erste Gehäuseauslaß (36) zur Rückführung von Blut zu dem Körper dient, und wobei die Strömungseinrichtung ein Plattenelement (50) aufweist, das benachbart zu und im großen und ganzen stromab von dem Einlaß (18) angeordnet ist, wobei zumindest das erste und das zweite Rippenelement (56, 57) an dem Plattenelement (50) entlang entweder der ersten bestimmten Richtung oder entlang der zweiten bestimmten Richtung angeordnet sind, um die Blutströmung von der Richtung, in der das Blut in das Gehäuse (12) durch den Einlaß (18) eintritt, entlang zumindest der ersten und der zweiten bestimmten Richtung umzulenken.
15. Vorrichtung (10) nach Anspruch 14, wobei die Rippenelemente (56, 57) an dem jeweiligen Plattenelement (50) angeordnet sind, um die Blutströmung in mehrere entsprechende bestimmte Richtungen zu lenken.
16. Vorrichtung (10) nach Anspruch 15, wobei die Rippenelemente (56, 57) im großen und ganzen quer bzw. transversal zu dem Plattenelement (50) angeordnet sind.
17. Vorrichtung (10) nach Anspruch 16, wobei das Plattenelement (50) eine Vielzahl von Öffnungen (54, 52) aufweist, die derart angeordnet sind, daß jedes Rippenelement (56, 57) eine entsprechende Öffnung (54, 52) aufweist, die dazu benachbart ist und im großen und ganzen stromauf von dem jeweiligen Rippenelement (56, 57) liegt.
18. Vorrichtung (10) nach Anspruch 14, die desweiteren eine Dichtungseinrichtung (104) aufweist, die zwischen dem Behälter (12) und der Saugregel-

kammer (94) fluidverbunden ist, um einen Rückfluß von Luft zu dem Patienten zu verhindern.

19. Vorrichtung (10) nach Anspruch 14, die desweiteren eine Entschäumeinrichtung (40) aufweist, die gestaltet und bemessen ist, um in dem Gehäuse (12) und in Fluidverbindung mit dem Fluid angeordnet zu werden, das durch die Strömungseinrichtung (50) gelenkt wird, bevor es durch den Auslaß (36) austritt.

Revendications

1. Appareil (10) destiné à la réception de fluides d'un patient, comprenant :

a) un boîtier (12) ayant une entrée (18) destinée à l'introduction de fluides dans le boîtier (12) et une sortie (36) destinée à la sortie des fluides du boîtier (12), et

b) un dispositif (50) de circulation disposé dans le boîtier (12) et destiné au moins à diriger les fluides entrant par l'entrée (18) afin qu'ils s'écoulent dans des directions prédéterminées,

caractérisé en ce que le dispositif de circulation (50) comprend :

1) un premier organe à nervure (56) adjacent à l'entrée (18), positionné en aval de l'entrée de façon générale et le long d'une première direction prédéterminée, et ayant une configuration et une dimension telles qu'une première partie au moins du fluide entrant par l'entrée (18) tombe sur le premier organe à nervure (56) et est ainsi dirigée dans la première direction prédéterminée du premier organe à nervure (56), et

2) un second organe à nervure (57) adjacent au premier organe à nervure (56) et en aval de façon générale de celui-ci, positionné dans une seconde direction prédéterminée différente de la première direction prédéterminée et ayant une configuration et des dimensions telles que la première partie au moins du fluide et la partie restante du fluide pénétrant par l'entrée (18) tombent sur le second organe à nervure (57) et sont ainsi dirigées dans la seconde direction prédéterminée du second organe à nervure (57).

2. Appareil (10) selon la revendication 1, dans lequel le dispositif de circulation (50) comporte plusieurs organes à nervures (56, 57) placés près de l'entrée (18) les uns près des autres et ayant des configurations et dimensions telles qu'ils donnent plusieurs directions prédéterminées correspondantes dans

lesquelles des parties au moins des fluides peuvent s'écouler.

3. Appareil (10) selon la revendication 1, comprenant en outre un dispositif (40) de suppression de mousse dont la configuration et la dimension sont telles qu'il est placé dans le boîtier (12) et en communication avec le fluide dirigé par le dispositif de circulation (50) avant passage par la sortie (36).

4. Appareil (10) selon la revendication 1, dans lequel le fluide est au moins du sang d'une cavité corporelle et le boîtier (12) collecte le sang au moins de la cavité corporelle, l'entrée (18) du boîtier étant en communication avec la cavité corporelle, la sortie du boîtier comprenant une première sortie (36) destinée à renvoyer le sang vers le corps et une seconde sortie (24) destinée à être raccordée à une source d'aspiration (86), et dans lequel le dispositif de circulation comporte en outre un organe (50) en forme de plaque adjacent à l'entrée (18) et en aval de façon générale de celle-ci, le premier organe (56) et le second organe (57) à nervure au moins étant disposés sur l'organe (50) à plaque.

5. Appareil (10) selon la revendication 4, dans lequel les organes à nervure (56, 57) sont placés sur l'organe respectif à plaque (50) afin qu'ils dirigent le courant de sang dans plusieurs directions prédéterminées correspondantes.

6. Appareil (10) selon la revendication 5, dans lequel les organes à nervure (56, 57) sont disposés en direction générale transversale à l'organe à plaque (50).

7. Appareil (10) selon la revendication 6, dans lequel l'organe à plaque (50) a plusieurs orifices (54, 52) disposés dans cet organe de manière que chaque organe à nervure (56, 57) ait un orifice correspondant (54, 52) qui lui est adjacent et en amont de façon générale à l'organe respectif à nervure (56, 57).

8. Appareil (10) selon la revendication 4, comprenant en outre un dispositif (40) de suppression de mousse ayant une configuration et des dimensions telles qu'il est placé dans le boîtier (12) d'une manière telle que le sang s'écoule à travers le dispositif (40) de suppression de mousse avant de sortir par la première sortie (36) et d'être renvoyé au corps.

9. Appareil (10) selon la revendication 4, comprenant en outre une monture (64) de l'appareil qui comprend :

a) un premier organe de corps (68) ayant une première partie d'extrémité de forme générale

en C dont la configuration et les dimensions permettent la fixation à un support (62), et

b) un second organe de corps (66) ayant une première partie d'extrémité dont la configuration et les dimensions permettent le logement et la retenue du boîtier (12), le premier organe de corps (68) et le second organe de corps (66) étant couplés mutuellement à leurs secondes parties respectives d'extrémité afin qu'ils permettent un mouvement relatif de rotation à des positions distinctes.

10. Appareil (10) selon la revendication 1, dans lequel l'appareil (10) comprend un dispositif collecteur (86) destiné à la réception, à la collecte et au renvoi de fluides corporels, l'appareil (10) comprenant :

un réservoir qui contient le boîtier (12) et le dispositif de circulation (50), la sortie du boîtier comprenant une première sortie (36) des fluides du boîtier et une seconde sortie (24) destinée à être raccordée à une source d'aspiration (90), et

un dispositif (94) de commande d'aspiration ayant une première sortie (90) qui communique avec la seconde sortie (24) du boîtier (12) du réservoir et ayant une seconde sortie (98) destinée à communiquer avec l'atmosphère ambiante.

11. Appareil (10) selon la revendication 10, dans lequel le dispositif de circulation (50) comporte plusieurs organes à nervure (56, 57) disposés près de l'entrée (18) et les uns près des autres et ayant une configuration et des dimensions telles qu'ils forment plusieurs directions prédéterminées correspondantes dans lesquelles des parties des fluides au moins peuvent s'écouler.

12. Appareil (10) selon la revendication 10, comprenant en outre un dispositif d'étanchéité (104) couplé entre le réservoir et la chambre (94) de réglage d'aspiration afin que la circulation d'air en retour vers le patient soit évitée.

13. Appareil (10) selon la revendication 10, comprenant en outre un dispositif (40) de suppression de mousse ayant une configuration et des dimensions telles qu'il est placé dans le boîtier (12) et communique avec le fluide dirigé par le dispositif de circulation (50) avant passage par la première sortie (36).

14. Appareil (10) selon la revendication 10, dans lequel le boîtier (12) est destiné à collecter au moins du sang d'une cavité corporelle, l'entrée (18) du boîtier communiquant avec la cavité corporelle, la première sortie (36) du boîtier étant destinée à renvoyer le sang vers le corps, et le dispositif de

circulation comprenant un organe à plaque (50) placé près de l'entrée (18) et en aval de celle-ci de façon générale, le premier et le second organe à nervure au moins (56, 57) étant placés sur l'organe à plaque (50) le long de la première direction prédéterminée ou le long de la seconde direction prédéterminée afin que le courant de sang provenant de la direction dans laquelle le sang pénètre dans le boîtier (12) par l'entrée (18) soit dévié le long de la première et de la seconde direction prédéterminées au moins.

15. Appareil (10) selon la revendication 14, dans lequel les organes à nervure (56, 57) sont disposés sur l'organe respectif à plaque (50) afin qu'ils dirigent le courant de sang dans plusieurs directions prédéterminées correspondantes.

16. Appareil (10) selon la revendication 15, dans lequel les organes à nervure (56, 57) sont disposés de façon générale en direction transversale à l'organe à plaque (50).

17. Appareil (10) selon la revendication 16, dans lequel l'organe à plaque (50) a plusieurs orifices (54, 52) disposés de manière que chaque organe à nervure (56, 57) possède un orifice correspondant (54, 52) qui lui est adjacent et qui est en amont de l'organe respectif à nervure (56, 57) de manière générale.

18. Appareil (10) selon la revendication 14, comprenant en outre un dispositif (104) d'étanchéité couplé entre le réservoir (12) et la chambre (94) de réglage d'aspiration afin qu'il empêche la circulation en sens inverse de l'air vers le patient.

19. Appareil (10) selon la revendication 14, comprenant en outre un dispositif (40) de suppression de mousse dont la configuration et les dimensions sont telles qu'il peut être placé dans le boîtier (12) et en communication avec le fluide dirigé par le dispositif de circulation (50) avant le passage par la sortie (36).

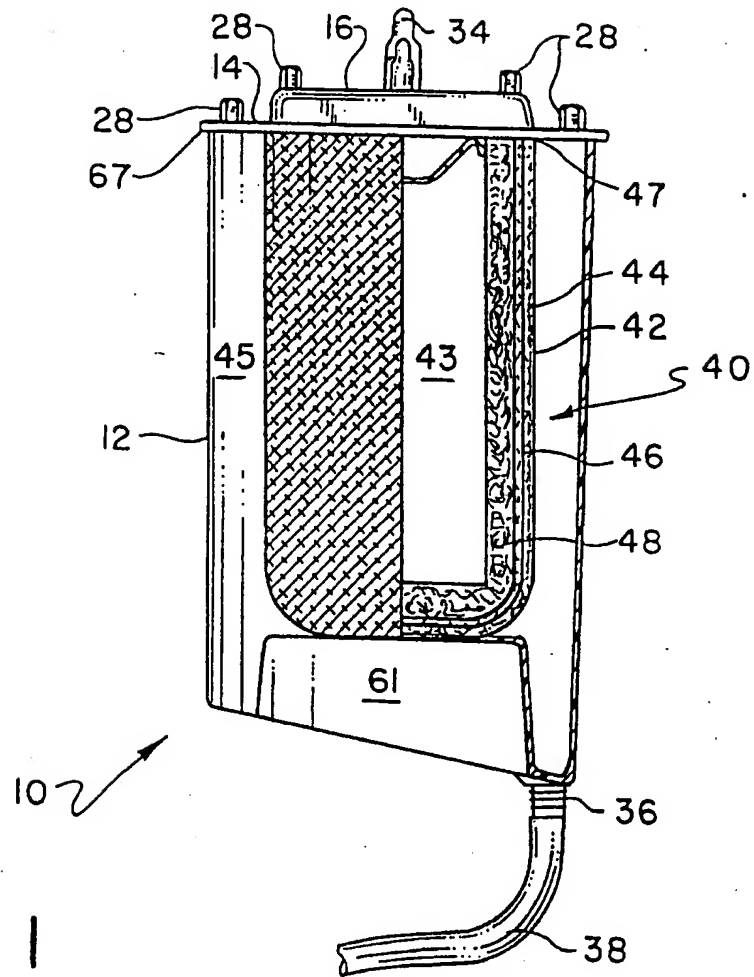


FIG. 1

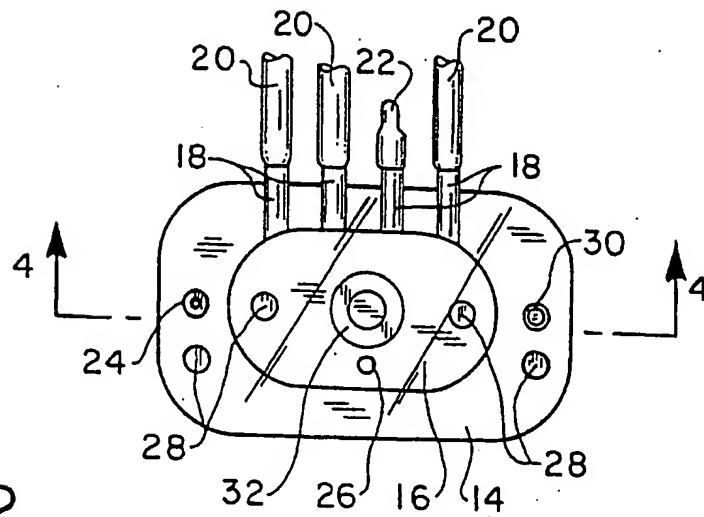


FIG. 2

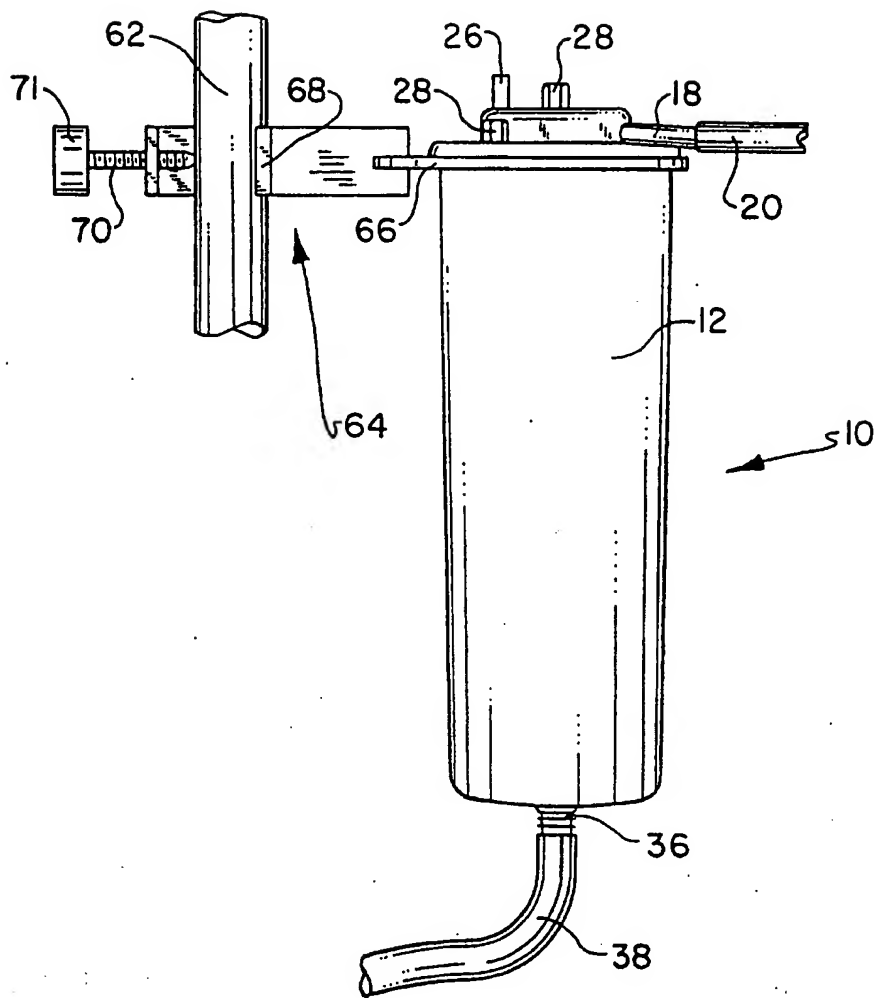


FIG. 3

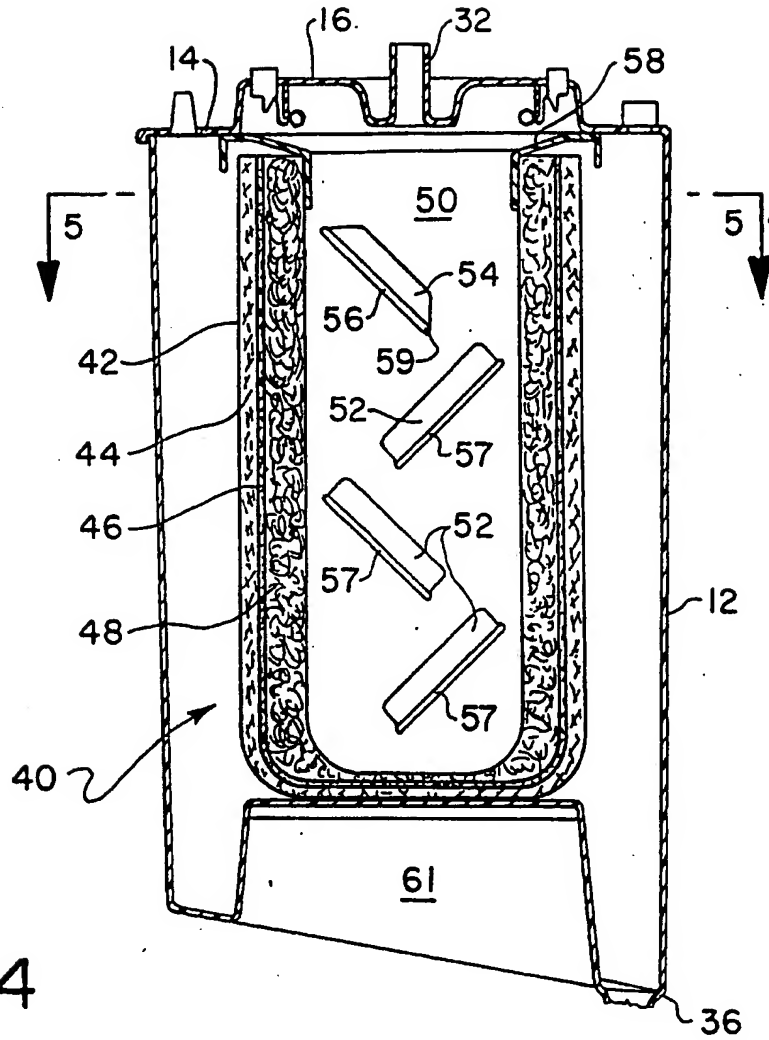


FIG. 4

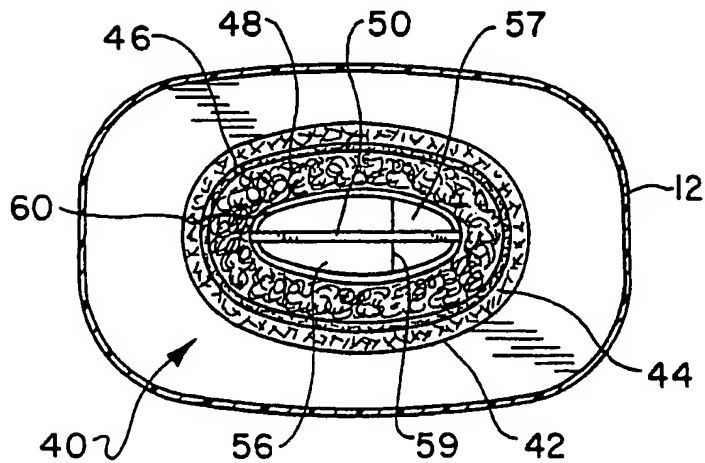


FIG. 5

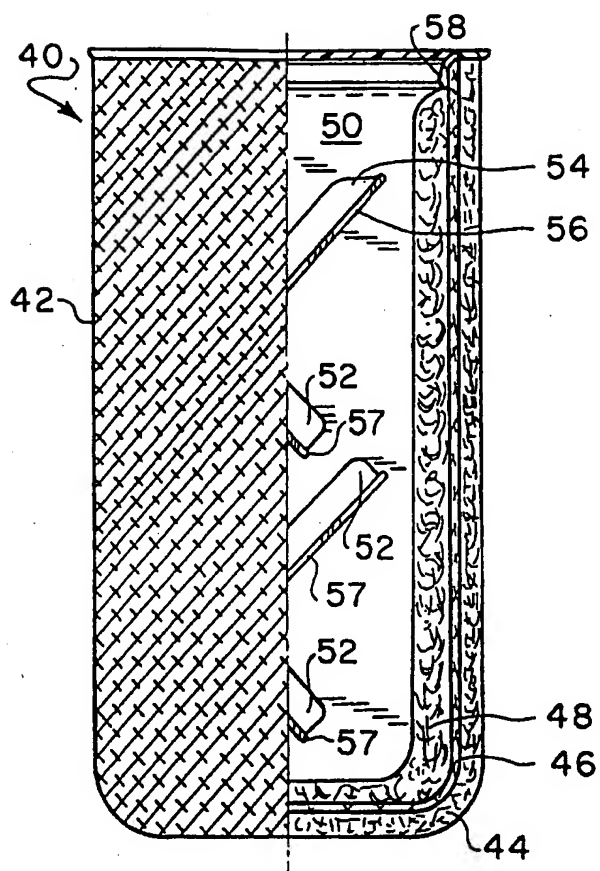


FIG. 6

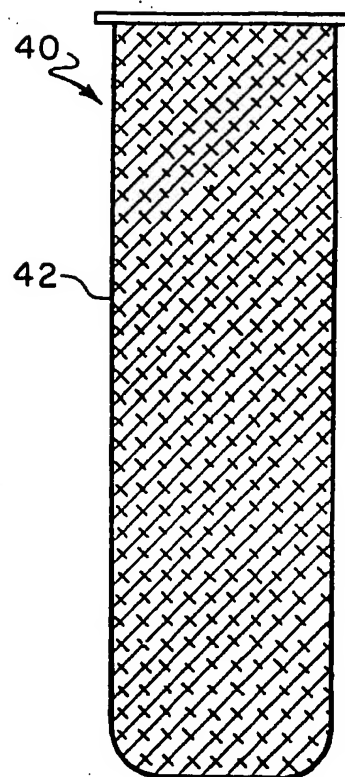


FIG. 8

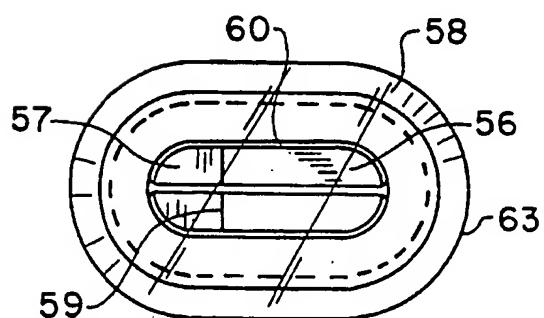


FIG. 7

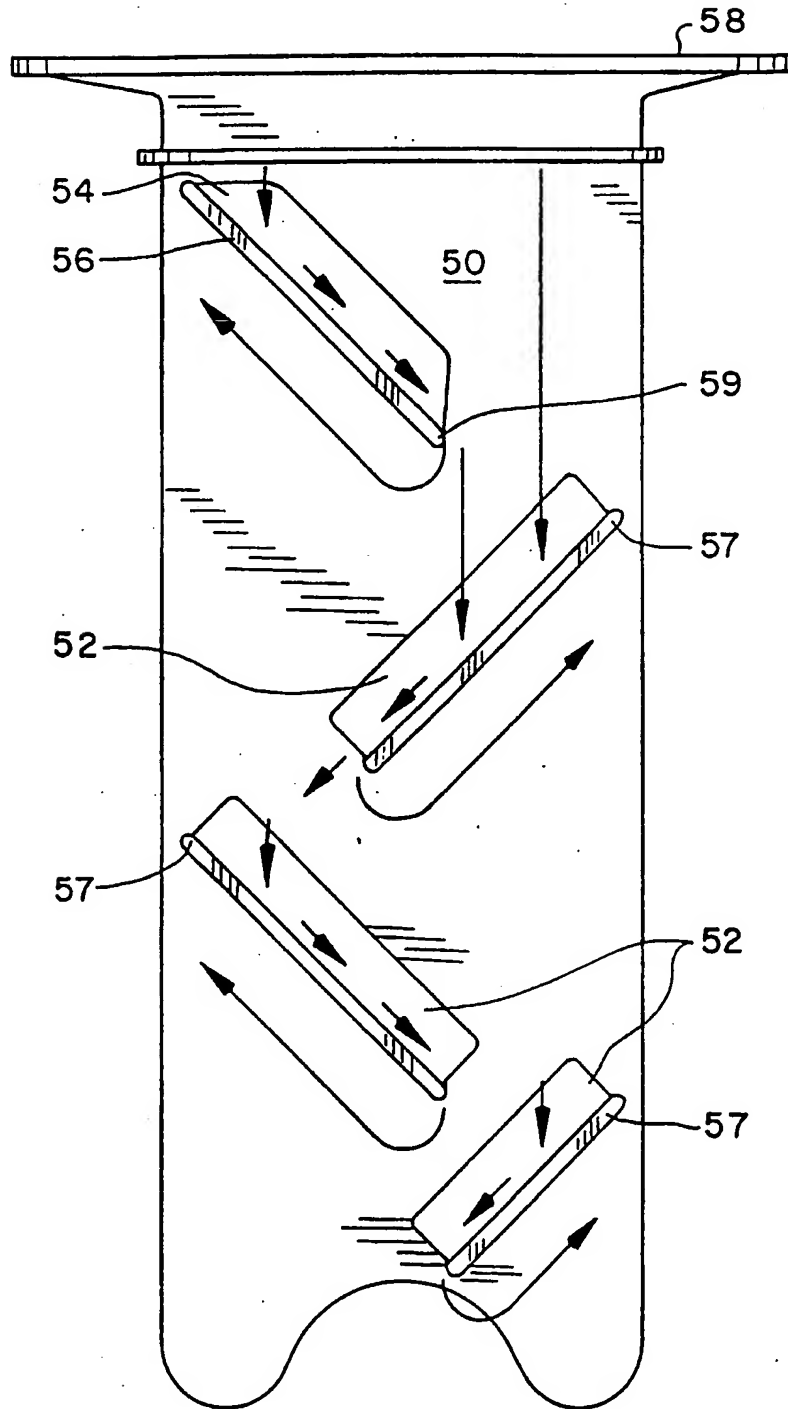


FIG. 9

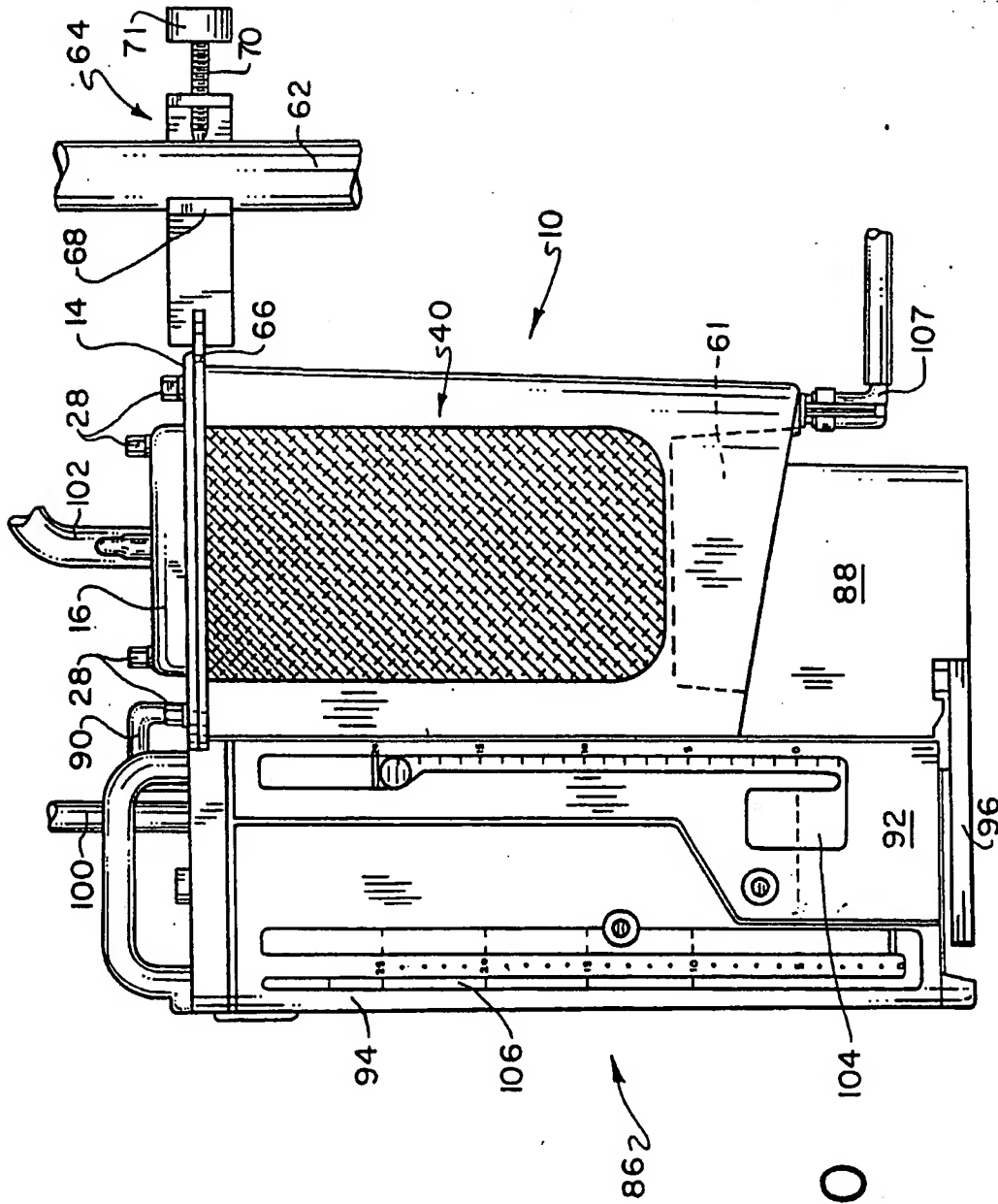
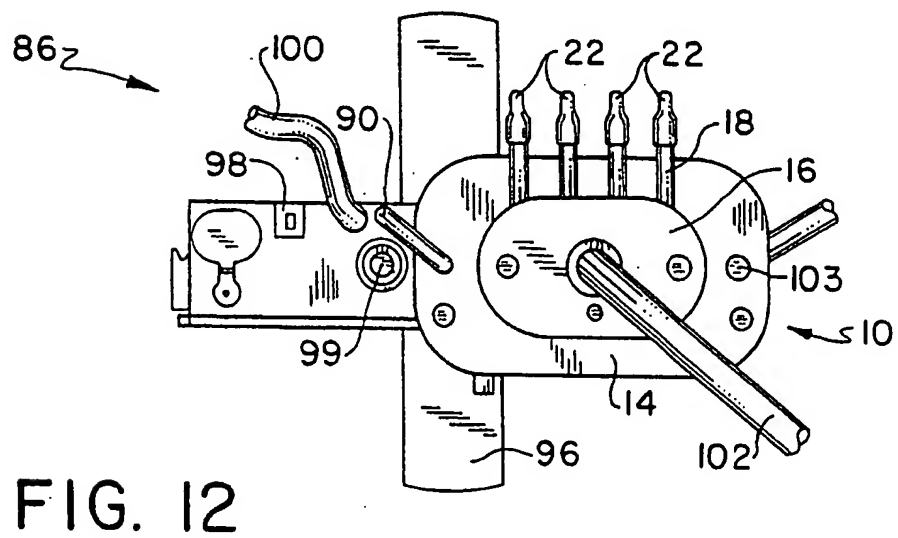
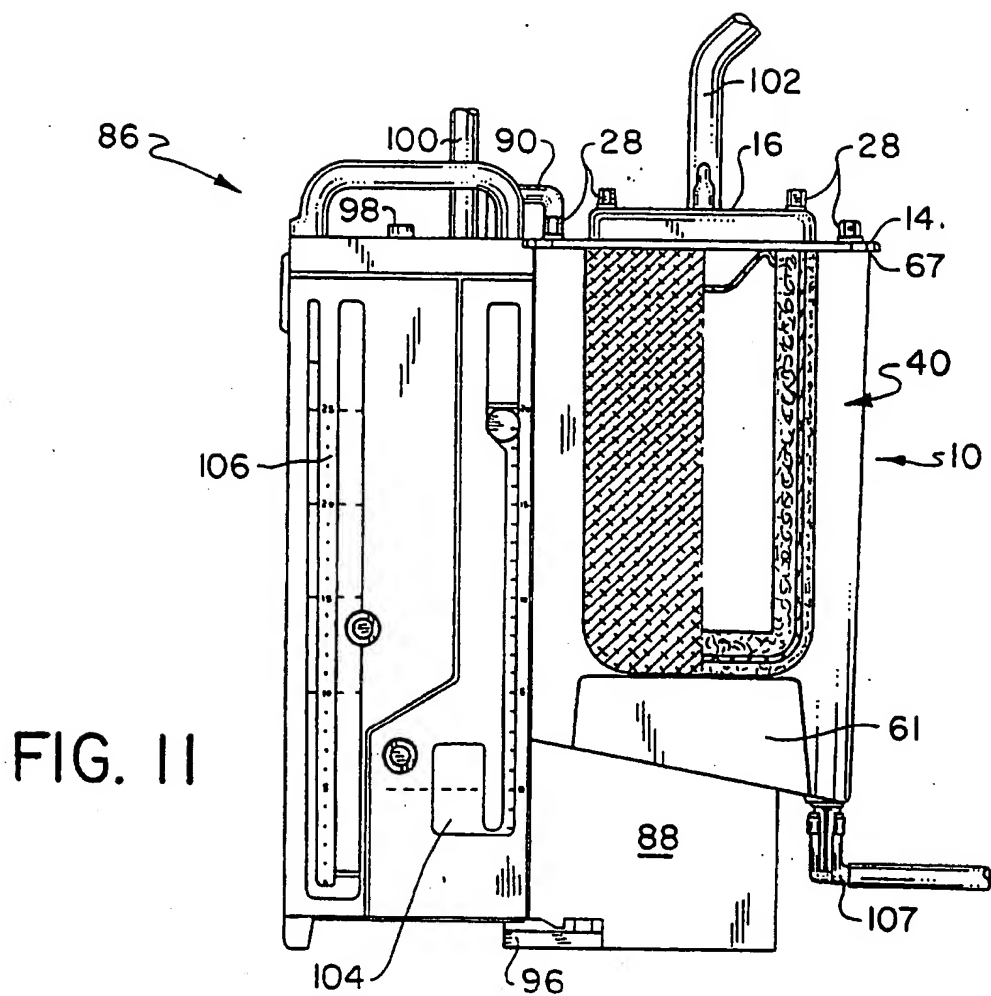


FIG. 10



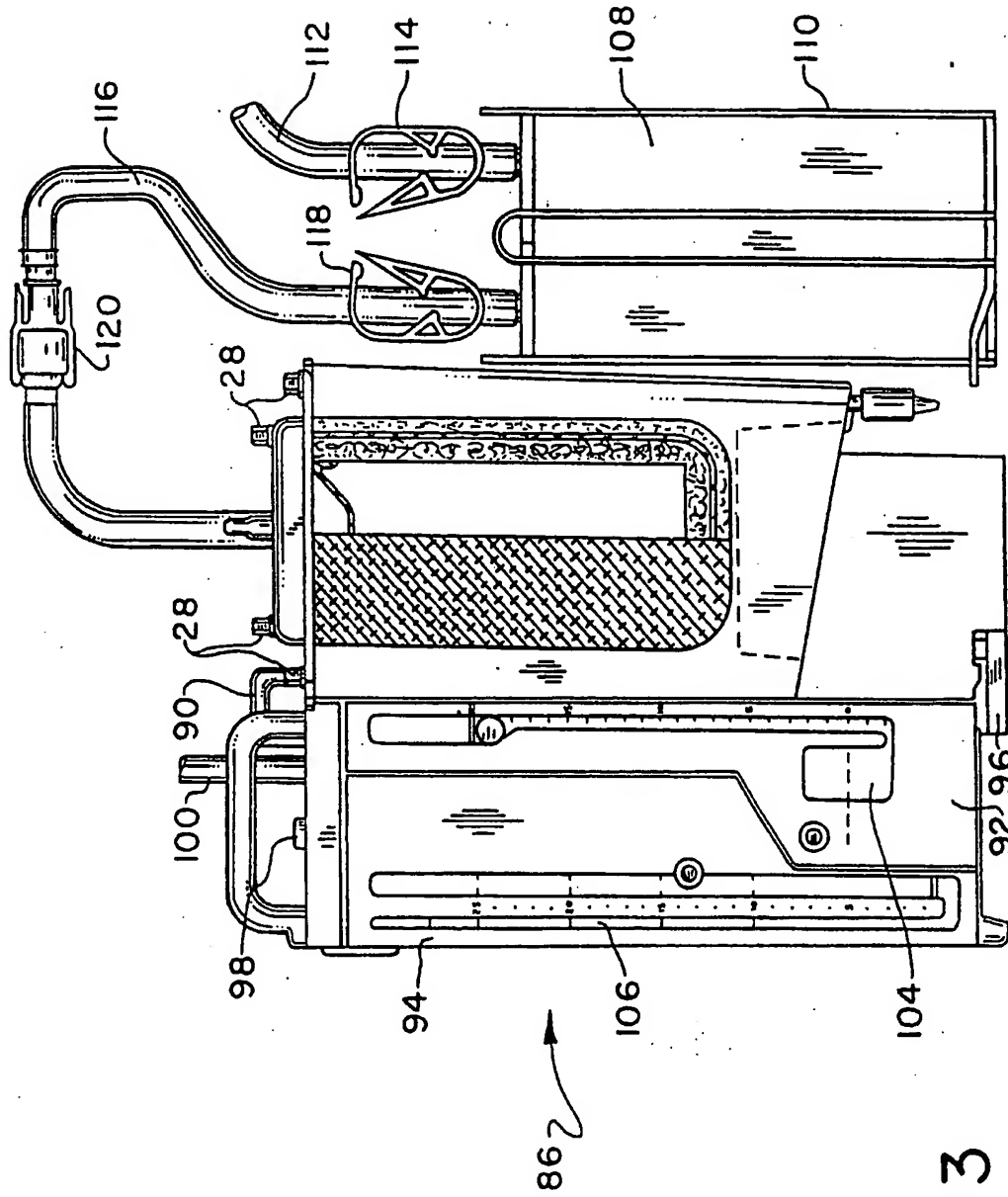


FIG. 13

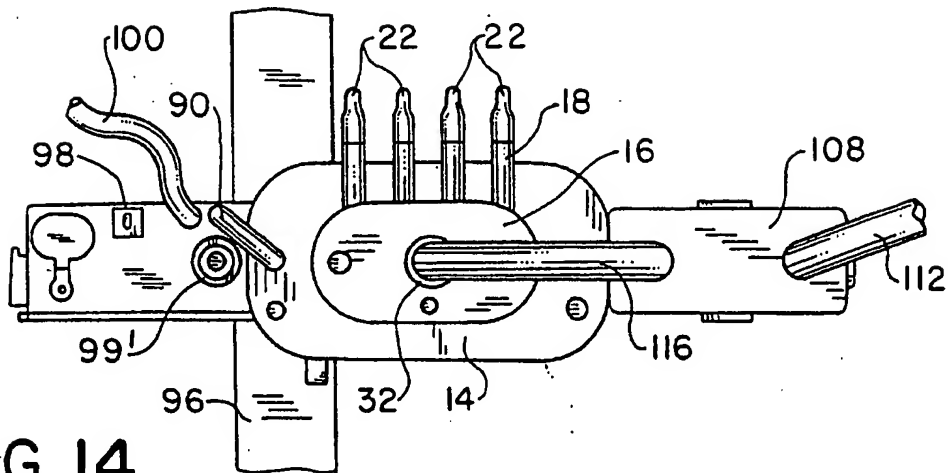


FIG. 14

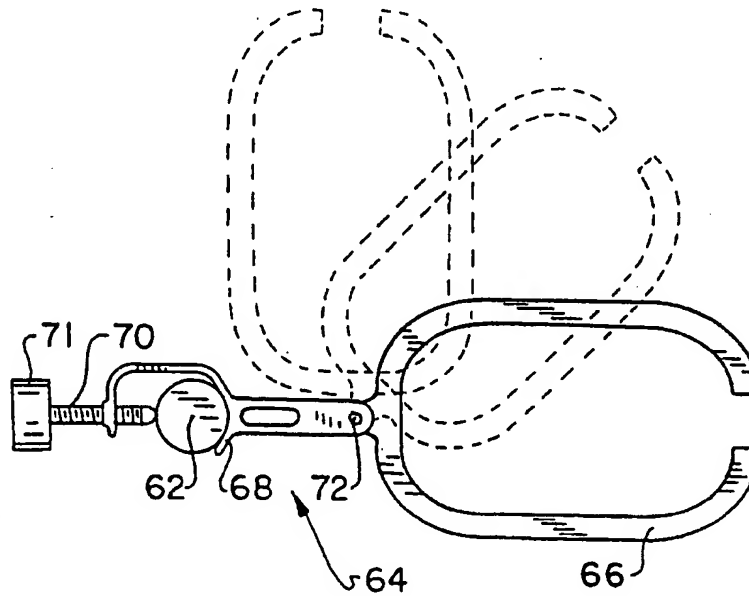


FIG. 15

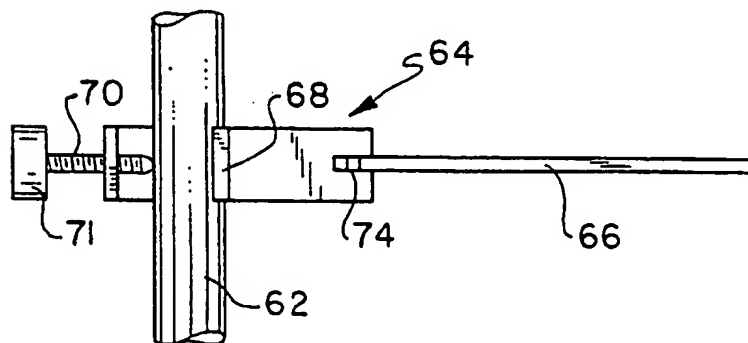


FIG. 16

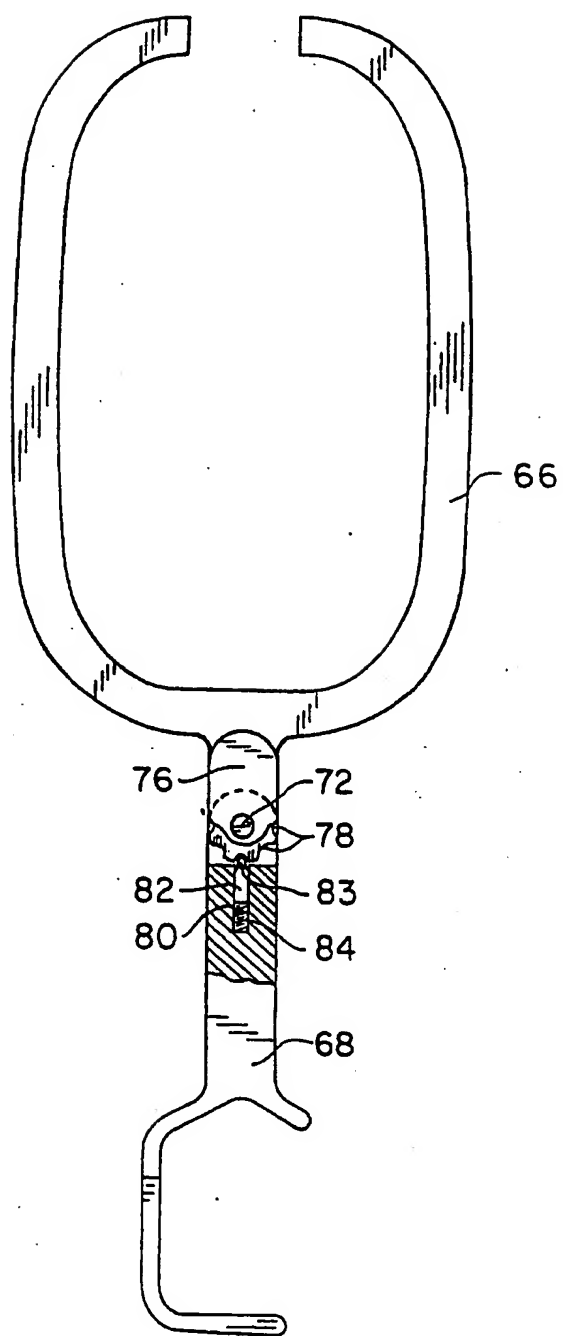


FIG. 17

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